CLINICAL INVESTIGATOR TRAINING COURSE (CITC)

November 13-15, 2018
Tommy Douglas Conference Center (TDCC), 10000 New Hampshire Ave., Silver Spring, MD 20903

AGENDA

DESCRIPTION

The clinical investigator training course is designed for physicians, nurses, pharmacists and other healthcare professionals involved in clinical trials. Lectures presented by senior FDA experts as well as guest lecturers from industry and academia explore the scientific, regulatory and ethical aspects of clinical trials. They also include discussions of non-clinical, early clinical, and phase 3 studies, issues in the design and analysis of trials, safety and ethical considerations and FDA regulatory requirements related to the performance and evaluation of clinical studies. FDA lecturers are from the Center for Drug Evaluation and Research (CDER), Center for Devices and Radiological Health (CDRH), and the Center for Biologics Evaluation and Research (CBER).

LEARNING OBJECTIVES

After completion of this activity, the participant will be able to:

1. Explain the responsibilities of an investigator conducting a clinical trial.
2. Describe what to look for in drugs being studied in a clinical trial.
3. Describe the basic concepts of clinical trial design.
4. Review clinical data for sources of bias and error.

REFERENCES

1. Title 21, Chapter I, Subchapter A, parts 50 (protection of human subjects), 54 (financial disclosure by clinical investigators), and 56 (IRBs)
2. Title 21, Chapter I, Subchapter D, parts 300-499 (drugs for human use)
3. Title 21, Chapter I, Subchapter F, parts 600-680 (biologics)
4. Title 21, Chapter I, Subchapter H, parts 800-898 (medical devices)

TARGET AUDIENCE

This activity is intended for physicians, pharmacists, nurses, researchers and others who are responsible for the conduct of clinical trials.

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TUESDAY, NOVEMBER 13TH		
7:30 - 8:20	Registration Sign-in and Distribution of Course Material	
SESSION 1: TRIAL DESIGN		
8:20 - 8:30	Welcome and Introduction	**Leonard Sacks, M.D.** FDA, CDER
8:30 - 9:00	FDA Structure and Mandate	**Leonard Sacks, M.D.**
9:00 - 10:00	The Design of Clinical Trials Part I	**Robert Temple, M.D.** FDA, CDER
10:00 - 10:15	BREAK	
10:15 - 10:45	The Design of Clinical Trials Part II	**Robert Temple, M.D.** FDA, CDER
10:45 - 11:00	Discussion and Questions	**Robert Temple, M.D.**
11:00 - 11:30	Clinical Outcomes Assessments	**Elektra Papadopoulos, M.D.** FDA, CDER
11:30 - 12:00	Electronic Technologies in Clinical Trials and clinicaltrials.gov	**Leonard Sacks, M.D.** **Bridget Foltz, M.S.** FDA, OC
12:00 - 12:15	Discussion and Questions	**Bridget Foltz, M.S.** **Elektra Papadopoulos, M.D.** **Leonard Sacks, M.D.**

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12:15 - 1:15	LUNCH	
1:15 - 1:45	Issues in Clinical Trial Designs for Devices	**Karen Ulisney, M.S.N., C.R.N.P** FDA, CDRH
1:45 - 2:15	Issues in Clinical Trial Design for Companion Diagnostic Devices	**Karen Bijwaard, M.S., RAC, MB(ASCP), CQA** FDA, CDRH
2:15 - 2:45	Issues in Clinical Trial Design for Rare Diseases	**Patroula Smpokou, M.D., FACMG** FDA, CDER
2:45 - 3:00	Discussion and Questions	**Karen Ulisney, M.S.N., C.R.N.P.** **Karen Bijwaard, M.S., RAC, MB(ASCP), CQA** **Patroula Smpokou, M.D., F.A.C.M.G.**
3:00 - 3:15	BREAK	

SESSION 2: ETHICS AND HUMAN SUBJECT PROTECTION

3:15 - 4:00	Informed Consent and Ethical Considerations in Clinical Trials	**Jon Mark Hirshon M.D., Ph.D., M.P.H.** University of Maryland
4:00- 4:45	Good Clinical Practice (GCP) Key Topics	**Bridget Foltz, M.S.** FDA, OC
4:45 - 5:00	Discussion and Questions	**Jon Mark Hirshon M.D., Ph.D., M.P.H.** **Bridget Foltz, M.S.**

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WEDNESDAY, NOVEMBER 14		
8:15	Sign-in	
SESSION 3: TRIAL POPULATIONS AND SAFETY		
8:30 - 9:00	FDA Perspective on International Studies	**Kassa Avalew, M.D., M.P.H.** FDA, CDER
9:00 - 9:30	Clinical Discussion of Specific Populations	**Su-Young Choi, Pharm.D., Ph.D.** FDA, CDER
9:30 - 10:00	Safety Considerations in Phase I Trials	**Joseph G. Toerner, M.D, M.P.H.** FDA, CDER
10:00-10:30	Safety Assessment in Clinical Trials and Beyond	**Yuliya Yasinskaya, M.D.** FDA, CDER
10:30-10:45	Discussion and Questions	**Kassa Avalew, M.D., M.P.H.** **Su-Young Choi, Pharm.D., Ph.D.** **Joseph G. Toerner, M.D, M.P.H.** **Yuliya Yasinskaya, M.D.**
10:45-11:00	BREAK	

U.S. Food and Drug Administration | Center for Drug Evaluation and Research
Office of Communication | Division of Drug Information | Small Business and Industry Assistance
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SESSION 4: INVESTIGATOR RESPONSIBILITIES		
11:00 - 11:30	Investigator Responsibilities-Regulation and Clinical Trials Part I	**Cynthia Kleppinger, M.D.** FDA, CDER
11:30 - 12:00	Investigator Responsibilities- Regulation and Clinical Trials Part II	**Cynthia Kleppinger, M.D.**
12:00 - 12:15	Discussion and Questions	**Cynthia Kleppinger, M.D.**
12:15 - 1:15	LUNCH	
SESSION 5: STATISTICAL CONSIDERATIONS		
1:15 - 2:00	The Analysis of Investigator Data, Sources of Bias and Error	**Susan Ellenberg, Ph.D.** University of Pennsylvania
SESSION 6: UNDERSTANDING THE INVESTIGATOR BROCHURE: NON-CLINICAL AND EARLY CLINICAL STUDIES		
2:00 - 2:30	CMC and the Investigator Brochure: Ensuring the Quality of a Drug is used in a Clinical Trial	**Erika Englund** FDA, CDER
2:30 - 3:15	Pharmacology/Toxicology in the Investigator Brochure	**Brenda Gehrke, Ph.D.** FDA, CDER

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3:15 - 3:30	Discussion/Questions	**Susan Ellenberg, Ph.D.** **Erika Englund** **Brenda Gehrke, Ph.D.**
3:30 - 3:45	BREAK	
3:45 - 4:30	Clinical Pharmacology	**Shirley Seo, M.D.** FDA, CDER
4:30 - 5:00	Biosimilar Biological Products	**Sue Lim, M.D.** FDA, CDER
5:00 - 5:15	Discussion/ Questions	**Shirley Seo, M.D.** **Sue Lim, M.D.**

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THURSDAY, NOVEMBER 15		
SESSION 7: INDs AND IDEs FROM START TO FINISH *Select a breakout session for drugs, devices, or biologics.*		
8:15	Sign-in	
Session 1A 8:30- 9:30	Center for Drug Evaluation and Research: How to Put together an IND Submission	**Judit Milstein, D.Sc.** FDA, CDER **Ei Thu Z. Lwin, Pharm.D.** FDA, CDER
Session 1B 8:30 - 9:30	Center for Biologics Evaluation and Research: Putting Together Your IND Application (CBER): CMC, Preclinical Testing and Clinical Trial Design Expectations to Ensure Safety for a First-in-Human Clinical Investigation	**Donald Fink, Ph.D.** FDA, CBER **Allen K. Wensky, Ph.D.** FDA, CBER **Rachel Witten, M.D.** FDA, CBER
Session 1C 8:30 - 9:30	Center for Devices and Radiological Health: How to Put together an IDE Submission: Safety and Effectiveness	**Jiping Chen, M.D., Ph.D., M.P.H.** FDA, CDRH **Joshua Chetta, Ph.D.** FDA, CDRH **Nadezda Radoja, Ph.D.** FDA, CDRH
9:30-9:45	BREAK	

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Session 2A 9:45 - 10:45	Center for Drug Evaluation and Research Repeat of Session 1A	
Session 2B 9:45 - 10:45	Center for Biologics Evaluation and Research Repeat of Session 1B	
Session 2C 9:45 - 10:45	Center for Devices and Radiological Health Repeat of Session 1C	
10:45 - 11:00	BREAK *Breakout groups combine into main training room.*	
11:00 - 11:30	Clinical Investigator Site Inspections- What to Expect	**Michelle Anantha, MSPAS, PA-C, RAC** FDA, CDER
SESSION 8: PATIENT PERSPECTIVE		
11:30 - 12:00	Patient Perspective/ Engagement in Drug Development	**Pat Furlong** *Founding President & CEO* Parent Project Muscular Dystrophy
12:00 - 12:15	Discussion/Questions	**Michelle Anantha, MSPAS, PA-C, RAC** **Pat Furlong**
12:15-1:15	LUNCH	

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SESSION 9 SAFETY AND EFFICACY - SPECIAL TOPICS		
1:15 – 1:45	Phase I Development Oncology- Investigator's Perspective	**Edward Sausville, M.D., Ph.D., F.A.C.P.** University of Maryland
1:45 - 2:15	Hepatotoxicity	**Mark Avigan, M.D.** FDA, CDER
2:15 - 2:45	Special Cardiac Safety Concerns	**Shari Targum, M.D.** FDA, CDER
2:45 - 3:15	Human Genetics in Therapeutic Development and Clinical Trials	**Alan R. Shuldiner, M.D.** University of Maryland
3:15 - 3:30	Discussion, Explain Evaluation Process, Wrap-up and Adjourn	**Mark Avigan** **Leonard Sacks M.D.** **Edward Sausville, M.D., Ph.D., F.A.C.P.** **Alan R. Shuldiner, M.D.** **Shari Targum, M.D.**